DOM07 – Practices for Quality Corrective Action

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1. Background

1.1 Quality corrective action shall be implemented when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

1.2 The purpose of quality corrective action is to bring about continuous improvement and is not considered punitive in nature. These practices specify steps and requirements to ensure that nonconformity is corrected, that the effect(s) on prior work products or records, if appropriate, is remediated, and recurrence is minimized. These practices also satisfy the requirements of the Department of Forensic Sciences (DFS) Forensic Science Laboratory (FSL) *Quality Assurance Manual*, the accreditation standards under ISO/IEC 17025:2005, and supplemental standards.

2. Definitions

2.1 For purposes of this document, the following terms shall have the designated meanings:

CSS: Crime Scene Sciences
DFS: Department of Forensic Sciences
DOM: Departmental Operations Manual
FSL: Forensic Science Laboratory
PHL: Public Health Laboratory
Q-CAR: Quality Corrective Action Report

3. Scope

3.1 These practices are applicable to valid nonconformities identified by all DFS personnel, internal or external customers, internal or external auditors/assessors, or through feedback, casework and/or proficiency tests. These practices may not apply to maintenance issues or situations that are minor in nature and can be quickly and effectively dealt with within the affected unit.

4. Responsibilities

4.1 The Division Director, *Deputy Director of* Quality, Directorate member and/or *Laboratory* Manager will:

4.1.1 Receive/initiate a Quality Corrective Action Report.
4.1.2 Determine if the *nonconformity is* a significant condition adverse to quality.
4.1.3 Ensure that an individual is assigned the responsibility of handling the corrective action.
4.1.4 Specify the response due date *and the timeframe for the follow-up*.
4.1.5 Ensure that the adequacy of the quality corrective action plan is determined.
4.1.6 Ensure that the effectiveness of a quality corrective action is verified.
4.1.7 Inform laboratory staff and/or individual *analyst* of completion of Quality Correction Action Report process.
4.1.8 Will determine if examinations are suspended and/or reports of examination(s) are withheld during an investigation.
4.1.9 Authorize the resumption of work.

4.2 The *Deputy Director of* Quality and Division Quality personnel will:

4.2.1 Ensure that the progress of a corrective action is tracked.
4.2.2 Establish the date and ensure the effectiveness verification is performed as necessary *within the established timeframe*.
4.2.3 Complete additional tasks regarding quality corrective action requests as defined in the CSS, FSL and/or PHL Quality Assurance Manual (s).

4.3 Individual(s) responsible for handling a corrective action will:

4.3.1 Receive/identify a potential quality corrective action.
4.3.2 Determine the root cause of the *nonconformity* and document the level.
4.3.3 Plan and implement corrective actions to remediate the *nonconformity* and prevent recurrence.
4.3.4 Return the Quality Corrective Action Report to the *Deputy* Director *of* Quality and *the initiating Laboratory* Manager by the due date.
4.3.5 Provide objective evidence of quality corrective action completion to the *Deputy* Director *of* Quality *and the initiating Laboratory* Manager.

5 Practices

5.1. Quality corrective actions will begin with an investigation to determine the root cause(s) of the problem. Next, a determination will be made as to the level of the nonconformity (1 or 2) and a Quality *Corrective Action Report* will be issued.

5.1.1 A Level 1 Nonconformity is a situation or condition that directly affects, and has fundamental impact, on the quality of the work product.

5.1.2 A Level 2 Nonconformity is a situation or condition which may affect the quality of the work but does not, to any significant degree, affect the fundamental reliability of the work product.

5.1.3 Quality corrective actions will be initiated in a timely manner to minimize the impact of the nonconformity.

5.1.4 Where necessary, the contributor will be notified of the non-conformity. Examination may be suspended and/or *Reports of Examination* withheld during an investigation. If appropriate, an amended report will be issued.

5.2 Root Cause Analysis

5.2.1 Root cause analysis requires an in-depth investigation of the underlying causation factors rather than cursory symptom analysis. A process review to include technical procedures, instrumentation utilization and maintenance, controls and standards requirements and employee performance may be required.

5.3 Quality Corrective Action Selection

5.3.1 An appropriate corrective action will be initiated by the Division Director, Deputy Director of Quality, Directorate member and/or Laboratory Manager. The allegation of nonconformity, causation review, findings and quality corrective action will be recorded on a Quality *Corrective Action Report*. This report identifies the root cause of the problem, the level of nonconformity, measures taken to properly correct the problem to a degree appropriate to the magnitude and risk, and post-corrective action monitoring requirements to avoid recurrence. When quality corrective action is needed, any potential corrective actions are identified. The action step (s) are selected and implemented to most likely eliminate the problem and to prevent recurrence. Any required changes resulting from corrective action investigations shall be documented and implemented.

5.3.1.1 A quality corrective action taken as a result of a Level 1 non-conformity must include the analysis of another (new) set of comparable samples by the person(s) responsible for the non-conformity and a review of comparable casework.

5.3.1.2 A quality corrective action taken as a result of a Level 2 non-conformity must include a review of comparable casework and may include analysis of another (new) set of comparable samples by the person(s) responsible for the inconsistency.

5.4 Quality Corrective Action Monitoring

5.4.1 All resulting approved quality corrective action recommendations shall be implemented, subsequently monitored and documented for compliance and effectiveness. Monitoring may be accomplished by subsequent audits. A file shall be kept by the Deputy Director of Quality of all corrective action processes for auditing compliance.

5.5 Quality Corrective Action Closure Memo

5.5.1 When the corrective action has been verified to correct the issue, the Laboratory Manager, Division Director and/or Deputy Director of Quality shall inform the laboratory staff and/or individual analyst of the completion of the process. Memorandum should be the method used to convey this information.

5.5.1.1 Level 1 Nonconformity memos may include the affected Division
5.5.1.2 Level 2 Nonconformities may include the affected Unit

5.6 Nonconformance Audits

5.6.1 Situations that bring into question compliance with established policies or procedures may necessitate audits of the appropriate area(s) or of the entire quality system. These audits will be conducted and documented as set forth in Section 4.14 of the *FSL Quality Assurance Manual* and/or other appropriate *Division Quality Manuals*. If required, notification of quality corrective action measures and findings will be communicated to any affected contributor. All quality corrective action processes will be documented and maintained within the laboratory.

5.7 Nonconformance Evaluations

5.7.1 When an evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedure, the quality corrective action procedures will be promptly followed and tracked.

6 Documentation

6.1 The following records will be generated and retained for at least one accreditation cycle *or five years, whichever is longer*:

6.1.1 Quality Corrective Action Report with the associated responses.

7 References

7.1 ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland (current revision)

7.2 ASCLD/LAB-International® Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC (current revision)

7.3 Forensic Quality Services Supplemental Requirements for Forensic Testing, FQS ANSI-ASQ Accreditation Board, Tampa, FL (current revision)

7.4 Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision)

7.5 Forensic Science Laboratory Quality Assurance Manual (current revision)

7.6 Unit-specific *Quality Assurance Manual* (current revision)

7.7 Division-specific Quality Assurance Manuals

7.8 Record Retention Policy